

REMARKS

Claims 1-6, 8, 10-11, and 13-22 are pending in this application, of which claims 1, 3-6, 10, 14 and 19-22 have been amended. Claims 7, 9, 12 have been cancelled. No new matter has been added. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement including the prosecution history, namely office actions and responses, of related US Patent Application S.N. 10/669,203 is submitted herewith. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §102(b)

Claims 1, 2, 6, 8, 19 and 22 stand rejected under 35 U.S.C. §102(b), as being allegedly anticipated by U.S. Patent No. 5,749,894 ("Engelson"). In order to sustain a rejection under §102(b), each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicant respectfully submits that Engelson cannot support the § 102(b) claim rejections, because Engelson does not disclose each and every element recited in these claims, as amended.

Independent claims 1 and 19 have been amended herein to clarify that the delivering of energy is performed using an energy emitting element located outside the body. Engelson does not disclose or teach the heating of a vaso-occlusive device using an **energy emitting element located outside a body**. Rather, Engelson teaches using a light-emitting device that "*has been **introduced** into the region just outside the mouth of the aneurysm*" (Col 8, lines 48-51). Thus, the light emitting device in Engelson is located inside

of a blood vessel, which is inside the body. (See, e.g., Figs. 10D, 11D and 12C of Engelson).

For at least this reason, Applicant respectfully submits that independent claims 1 and 19, along with claims 2, 6, 8 and 22 which depend therefrom, are not anticipated by Engelson.

Claim Rejections - 35 U.S.C. §103

Claims 3, 10 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of US Pub 20040215124 ("Yamasaki"). The Examiner indicated in the office action that, in view of Yamasaki, it would have been obvious to one skilled in the art to deploy the vaso-occlusive device described in Engelson and position the body in a magnetic resonance imaging (MRI) device to apply magnetic field and thereby heat the vaso-occlusive device. Applicant respectfully disagrees.

The Supreme Court has recently addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. ____ (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR at page 14 of the slip opinion), and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17 of the slip opinion). While not specifically addressed by the Supreme Court in KSR, the prior art reference (or references when combined) must teach or suggest all the claim limitations (See MPEP §2143).

As discussed above, Engelson does not disclose heating a vaso-occlusive device using an energy emitting element located outside a body to release or activate bioactive agents at the treatment site when the vaso-occlusive device is heated (Claims 3, 10 and 13). Neither does Yamasaki.

Yamasaki discloses introducing an irritant in serum form into the aneurysm, causing the aneurysm to shrink *“over the course of several days or weeks”* (Yamasaki, paragraph 62 - 66). Although, MRI may be used to cure the irritant in Yamasaki, a method combining Engelson with Yamasaki, would not recite all the claims limitations of claims 3, 10 and 13. Certainly, Engelson does not suggest why such modification of a MRI use would be desirable because Engelson’s method requires a light-emitting device that *“has been introduced into the region just outside the mouth of the aneurysm”* in order to reform the polymers. Furthermore, even if a person skilled in the art would consider modifying the device of Engelson, in view of Yamasaki, such combination would still not teach or suggest a method for embolizing a target site by delivering magnetic resonance energy to a detached vaso-occlusive device from an energy emitting element outside of a body to release or activate bioactive agents when the device is heated, absent hindsight in view of the present application.

For at least these reasons, claims 3, 10 and 13 are believed patentable over the combination of Engelson and Yamasaki.

Claims 4, 17-18 and 20 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of Yamasaki, and further in view of USP 5,853,418 (“Ken”). Applicant respectfully disagrees. Claims 4 and 20 have been amended herein to clarify that the ferrous material comprised in the device is in sufficient concentration to

cause heating of the device in response to energy delivered by the magnetic resonance device. Ken states that a stretch-resisting member provided for a vaso-occlusive coil device may “optionally contain modest amounts of iron” (Col. 5, lines 1-2), and there is no mention or suggestion in Ken that such “modest amounts of iron” in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to energy delivered by an energy emitting device located outside the body when the coil is detached and implanted at a treatment site. In particular, there is no mention in Ken that the coil itself contains, or may optionally contain, any amount of iron, despite a detailed description of what materials the coils are made from (Col 4, lines 47-60).

Independent claim 14 and dependent claim 15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Yamasaki. The office action indicates that it would have been obvious to provide magnetic resonance to the device of Ken to heat the highly conductive material used in vaso-occlusive devices. Applicant respectfully disagrees. Ken discloses releasing a vaso-occlusive coil in the treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62) and, as indicated above, the coil having a stretch resistance member that may optionally contain “modest amounts of iron.” Yamasaki discloses adding an irritant to an aneurysm, where MRI energy may be used to cure such irritant. However, the application of energy in Ken is used to sever the joint that releases the coil from the delivery device into the treatment site, and not to heat the already detached device from the delivery catheter, as recited in claim 14. As discussed above, there is no evidence that the device of Ken comprises sufficient ferrous material to act as a heating member if exposed to the energy delivered by an MRI

system. Certainly, Ken does not suggest that such use of MRI energy would be effective to heat the device or otherwise desirable.

For at least these reasons, independent claim 14 is believed patentable over the combination of Engelson, Yamasaki and Ken. Dependent claims 4, 15, 17-18 and 20 are also believed patentable over such combination, for at least the same reasons.

Additionally, claims 5 and 21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of USP 6,740,094 ("Maitland"). Applicant respectfully disagrees. The office action alleges that Engelson discloses the claimed invention except for the energy source comprising an ultrasound device as disclosed in Maitland. Maitland discloses the activation and expansion of a shape memory actuator when heated to remove blockages in a blood vessel, wherein the energy delivered to the actuator may be ultrasounds waves (Col 6, lines 26-57). As discussed above, however, Engelson does not disclose the methods of claims 5 or 21. Further, modifying Engelson in view of Maitland will still not render the methods of claims 5 or 21, where the heating of the vaso-occlusive device is accomplished by an ultrasound energy emitting element located outside of the body, and where the heating releases or activates bioactive agents (claim 5) or heats the blood or tissue in the aneurysm (claim 21).

Claim 11 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of Yamasaki and in further view of USP 5,405,322 ("Lennox"). Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Yamasaki and in further view of Lennox. Lennox discloses a method for treating an aneurysm by heating the aneurysm wall with an electrical current generated between two electrodes located in a device inserted into the blood vessel (i.e., inside the body) (Col

4 lines 13-30). In contradistinction, the energy emitting element used in the methods of claims 11 and 16 is located outside the body, with no electrodes placed internally in the blood vessel. None of Engelson, Yamasaki or Ken discloses the claimed invention alone or in combination with Lennox.

CONCLUSION

In view of the foregoing amendments and remarks, allowance of all remaining claims is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, she is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,
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